UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

PLAINTIFFS' PROPOSED FINDINGS OF ULTIMATE FACT

Pursuant to paragraph 2 of the Court's Memorandum Endorsement dated October 20, 2022 (ECF No. 317), Plaintiffs hereby submit their Proposed Findings of Ultimate Fact, without evidentiary support. Pursuant to paragraph 3 of the Court's Memorandum Endorsement,

Plaintiffs will serve on Defendants their proposed findings of ultimate fact with evidentiary sources today.

- 1. Since at least 2007, Defendants have widely disseminated advertisements nationally and in the state of New York that expressly or impliedly claim that¹:
 - a. Prevagen improves memory;
 - b. Prevagen improves memory within 90 days;
 - c. Prevagen reduces memory problems associated with aging;
 - d. Prevagen provides other cognitive benefits, including but not limited to, healthy brain function, a sharper mind, and clearer thinking;
 - e. Prevagen is clinically shown to improve memory;
 - f. Prevagen is clinically shown to improve memory in 90 days;
 - g. Prevagen is clinically shown to reduce memory problems associated with aging;
 - h. Prevagen is clinically shown to provide other cognitive benefits, including, but not limited to, healthy brain function, a sharper mind, and clearer thinking.
- 2. Defendants made the challenged claims on multiple television stations and programs, both nationally and in the State of New York, from at least June 2015 to the present; on infomercials aired on dozens of New York television stations from at least October 2013 to at least April 2015; on their websites from at least 2015 to the present; and on their product packages and labels from at least October 2010 to the present. The number of airings of Defendants' television ads in New York, from June 2015 to present, was ______. The number of airings of Defendants' radio ads in New York, from June 2017 to present, was
- 3. Quincy Bioscience LLC did not use procedures generally accepted by experts in the relevant fields to yield accurate and reliable results in conducting and evaluating the Madison Memory Study, as Quincy Bioscience LLC failed, among other things, to properly maintain blinding, failed to document any subgroups for analysis before the study started, and failed to apply a proper statistical correction to the analyses of the subgroup data.
- 4. The Madison Memory Study does not show that Prevagen improves memory or provides other cognitive benefits in humans because, in addition to the flaws in how it was conducted, there was no statistically significant difference between Prevagen and placebo either in the study population as a whole or, after the application of a proper statistical correction, in any subgroup of the study population.
- 5. Between approximately January 2012 through September 2012, Defendants conducted the Memory Improvement Trial, an unreported randomized controlled trial focused on college

Because Defendants continue to advertise and sell Prevagen, Plaintiffs requested that they update certain interrogatory responses and their financial statement production at an appropriate date closer to trial. Plaintiffs anticipate relying on the updated responses in support of their proposed findings, including Findings Nos. 1-2 and 15-18 herein.

- students taking Prevagen, and that trial does not show that Prevagen improves memory or provides other cognitive benefits in humans.
- 6. Defendants' other human studies, including those that lack a placebo control, also do not show that Prevagen improves memory or provides other cognitive benefits in humans.
- 7. Defendants have not conducted any studies on the formulation of Prevagen consisting of apoaequorin and vitamin D, and existing literature on vitamin D does not show vitamin D improves memory or provides other cognitive benefits in humans.
- 8. Defendants' *in vitro* studies, canine research, and rat studies do not show that Prevagen improves memory or provides other cognitive benefits in humans.
- 9. The Corporate Defendants—Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC—are all wholly owned by Quincy Bioscience Holding Company, Inc., share a common business address and officers, and have been included together on consolidated financial and tax statements.
- 10. The Corporate Defendants' business activities are entwined around Prevagen—Quincy Bioscience Holding Company, Inc. wholly owns: Prevagen, Inc., which markets Prevagen, oversees the manufacturing of Prevagen, and sells Prevagen; Quincy Bioscience Manufacturing, LLC, which assists with the manufacturing of Prevagen; and Quincy Bioscience, LLC, the holder of Prevagen-related patents and trademarks.
- 11. Individual Defendant Mark Underwood has extensive control over the Corporate Defendants because, among other things, he is their co-founder, President, and Chief Operating Officer, is the largest individual shareholder of Quincy Bioscience Holding Company, Inc. and sits on its Board of Directors, has direct oversight over the Corporate Defendants' financial condition, research and development, and sales and marketing, oversees the development, conduct, and evaluation of the Corporate Defendants' scientific research, including the Madison Memory Study and the Memory Improvement Trial, and is responsible for Corporate Defendants' regulatory compliance, including correspondence with the Food and Drug Administration ("FDA") about the Defendants' advertising practices and scientific research.
- 12. Individual Defendant Mark Underwood participated in Defendants' deceptive advertising practices by, among other things, coming up with the idea to create Prevagen, being part of the marketing creative team for Prevagen, participating in creating advertisements to promote Prevagen, designing and editing the Prevagen product labels and packaging, appearing in advertisements on TV and radio to promote Prevagen, being the final decision-maker on final advertising claims, translating scientific data into marketing language, directing research programs and activities, overseeing the employees who conducted the Madison Memory Study, participating in drafting the Madison Memory Study's protocol, participating in discussions about which subgroups of the Madison Memory Study to analyze, co-authoring the 2011, 2014, and Winter 2016 Madison Memory Study write-ups, participating in preparing the August 2016 Madison Memory Study write-up, and presenting results of the

Madison Memory Study at the Alzheimer's Association International Conference in Paris in 2011.

- 13. Individual Defendant Mark Y. Underwood had knowledge or awareness of the Defendants' deceptive advertising practices because, among other things, he was involved in, and had oversight of, the Madison Memory Study, participated in developing Defendants' advertising claims, received a warning letter from the FDA issued on October 16, 2012 regarding research performed on Prevagen and claims appearing on the Corporate Defendants' websites, and was aware of criticisms raised by outside parties as to Corporate Defendants' research, including Corporate Defendants' human studies as well as research on Prevagen's mechanism of action.
- 14. There is no known mechanism of action, nor any plausible mechanism supported by reasonable precedent, for Prevagen to improve memory or provide other cognitive benefits.

| 15. Defendants' sales of Prevagen throughout the United States from 2011 to present, totaled bottles and in revenue. |
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| 16. Defendants' New York sales of Prevagen, from 2011 to present, totaled bottles and in revenue, at a price range of to |
| 17. From January 1, 2015 to present, Defendants spent on advertising and marketing of Prevagen. |
| 18. From January 1, 2011 to present, Defendants made a gross profit of and a net income of |
| Dated: November 21, 2022 |

FEDERAL TRADE COMMISSION

EDERAL TRADE COMMISSIO

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CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of November, 2022, I have caused service of the

foregoing—Plaintiffs' Proposed Findings of Ultimate Fact—to be made by electronic filing with

the Clerk of the Court using the CM/ECF system, which will send a Notice of Electronic Filing

to all counsel of record.

Dated: November 21, 2022

/s/ Annette Soberats

Annette Soberats

Federal Trade Commission

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